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*7/10/04***Related Application**

This application claims priority to U.S. Provisional Application No. 60/394,779, filed on July 10, 2002, the entirety of which is incorporated herein by reference.

Field of Invention

This invention relates to a spinal support coupling device. More specifically, the present invention relates to a spinal support coupling device for use in inserting coupling rods between screws inserted into a patient's spine.

Background of Invention

Support devices, utilized in spinal surgery, often include screws driven through the bones in the spinal column. The screws are subsequently connected by way of a metal rod or a plate after the screws have been inserted. These rods or plates are typically inserted through the screw heads, having complex mechanical connections, allowing for variable fixation angles. This approach, using variable angle screw heads, requires the heads to align to accommodate for an arc of a pre-defined radius. This enables the delivery of the connecting rod, shaped as an arc or a circle, with the same radius.

However, there are a number of shortcomings with such systems. For example, both screw heads have to be able to pivot to adjust for the fixed trajectory of the connecting rod. Additionally, because the extensions from the screws need to be secured to the device at a single point, there is limited flexibility when 5 positioning the device, making it more difficult to set up. Furthermore, because the prior art devices require that the screw extensions meet at a single point, manipulation of the screw heads and connecting rods involves more movement under the patient's skin and muscle, requiring substantially higher surgical skills and experience as well as a larger surgical incision through the patients back 10 muscles, relative to currently practiced methods for such surgeries.

Summary of Invention

The present invention looks to overcome the drawbacks associated with the 15 prior art by providing a more flexible means to connect the surgery device to the screws, limiting the size of the incision required and making manipulation of the screws and connecting rod easier for the surgeon.

To this end, in one embodiment of the present invention, a spinal support 20 coupling device is provided comprised of first and second radial frames, each pivotably coupled to a center pivot hinge. A traveling arm is provided, coupled to the first and second radial frames at the center pivot hinge. The traveling arm is

configured to rotate with respect to the first and second radial frames around the center pivot hinge.

A coupling rod is attached to the traveling arm and configured to connect a first and a second surgical screw, placed into a patient. The first and second radial frames are configured to retain corresponding first and second extension rods, 5 extending away from the top of the first and second surgical screws.

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Brief Description of the Drawings

The present invention will be further understood from the following description with reference to the accompanying drawings, in which:

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Fig. 1 is a front view of a spinal support coupling device, in accordance with one embodiment of the present invention;

10 Fig. 2 is a front view of surgical screws and extension rods fixed in a patient's back, in accordance with one embodiment of the present invention;

15 Fig. 3 is a side view of a spinal support coupling device from Figure 1, mounted on extensions rods, in accordance with one embodiment of the present invention;

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Fig. 4 is an illustration of a patient's back, wherein the spinal support coupling device may be used in accordance with one embodiment of the present invention;

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Fig. 5A is a cut-away close-up view of a surgical screw and extension rod being inserted into a patient's vertebrae, in accordance with one embodiment of the present invention;

Fig. 5B is a side view of a surgical screw and extension rod being inserted into the patient's vertebrae, in accordance with one embodiment of the present invention;

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Fig. 6 is a side view of surgical screws and extension rods fixed in a patient's back, in accordance with one embodiment of the present invention;

Fig. 7 is a side view of a spinal support coupling device from figure 1,
10 mounted on extensions rods extending from a patient's spine, in accordance with one embodiment of the present invention; and

Fig. 8 is a side view of a spinal support coupling device from figure 1,
15 mounted on extension rods extending from a patient's spine, in accordance with one embodiment of the present invention.

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Detailed Description

The present invention comprises a spinal support coupling device 10. In one embodiment, as illustrated in Fig. 1, coupling device 10 is comprised principally of 5 a traveling arm 20, a center pivot hinge 30 and first and second radial frames 44A and 44B.

As illustrated in Fig. 1, traveling arm 20 is of a particular length (L) and maintains a piercing arm 22 mounted at the top. Piercing arm 22, attached perpendicularly at the top of traveling arm 20, preferably has a curvature with a 10 radius (L), and is extended along arc (A), defined by a circle with radius (L). The bottom portion of traveling arm 20, distal to piercing arm 22, is attached to a center pivot hinge 30 at a center point (P).

In an alternative arrangement, piercing arm 22 may maintain a different shape that does not have a curvature with a radius (L) that corresponds to the length 15 of traveling arm 20, or extend along arc (A). For example, piercing arm 22, may be configured as a straight bar, a v-shaped bar, or even a curved bar with curvature having a radius other than (L).

Additional alternative arrangements may include a piercing arm 22 attached to traveling arm 20 such that piercing arm 22 extends forward either in a line, 20 tangent to the curve having a radius of (L), or it may be aimed along an arc (A) of a circle having a radius (L). Any shaped piercing arm 22, attached to traveling arm

20 in substantially the same direction, for use in a similar coupling device 10, is
within the contemplation of the present invention.

As illustrated in Fig. 1, a coupling rod 80 is removably attached to the end of
piercing arm 22. The length of coupling rod 80 is preferably roughly equal to the
5 distance between two vertebrae on a patient's back, which need to be anchored
together. Coupling rod 80, attached to the end of piercing arm 22, preferably has a
curvature with a radius (L), and is extended along arc (A), defined by the circle with
a radius (L). The front portion of coupling rod 80 is tapered so as to allow easier
movement inside of the patient.

10 In an alternative arrangement, coupling rod 80 may maintain a different
shape that does not have a curvature with a radius (L) or extend along arc (A). For
example, coupling rod 80, may be configured as a straight bar, a v-shaped bar, or
even a curved bar with curvature having a radius other than (L). The shape of
coupling rod 80 may vary, depending on the shape of the particular vertebrae to be
15 connected.

For the purposes of illustration, the preferred shapes of coupling rod 80 and
piercing arm 22, with curvatures with a radius (L), extended along arc (A), defined
by the circle with a radius (L), are used throughout.

As illustrated in Fig. 1, center pivot hinge 30, attached to traveling arm 20, is
20 coupled to first and second center pivot hinge connecting arms 32A and 32B. First
and second center pivot hinge connecting arms 32A and 32B preferably extend
downwardly at an angle from center pivot hinge 30 as described in more detail

below, although the invention is not limited in this respect. For example, in another embodiment of the invention, pivot hinge connecting arms 32A and 32B extend at variable angles from center pivot hinge 30, including angles in an upward direction, where the angles at which connecting arms 32A and 32B extending from pivot hinge 30 may be the same or different from each other.

5 First and second radial frame connection arms 42A and 42B attached to connecting arms 32A and 32B respectively and preferably extend away from first and second center pivot hinge connecting arms 32A and 32B, from points distal to center pivot hinge 30.

10 First and second radial frames 44A and 44B are preferably attached at the ends of radial frame connecting arms 42A and 42B respectively, at points distal to center pivot hinge connecting arms 32A and 32B. Radial frames 44A and 44B extend radially from radial frame connection arms 42A and 42B with a curvature preferably having a radius (L), corresponding to the length of traveling arm 20, which extends along an arc (A), defined by the circle with a radius (L). In this configuration, radial frames 44A and 44B that are attached to center pivot hinge 30 via connecting arms 32A, 32B, 42A and 42B, such that circles, having arcs (A), drawn through both first and second radial frames 44A and 44B, would intersect at center point (P), located at center pivot hinge 30.

15 20 The formation and connections between center pivot hinge 30, first and second pivot hinge connecting arms 32A and 32B, first and second radial frame

connecting arms 42A and 42B and radial frames 44A and 44B can be set in several different arrangements while still maintaining the proper function of device 10.

For example, in a first preferred configuration, pivot hinge connecting arms 32A and 32B are independently attached to center pivot hinge 30 so as to be 5 independently movable with respect to one another. In this arrangement, the angle between first pivot hinge connecting arm 32A and second pivot hinge connecting arm 32B may vary based on how device 10 is ultimately connected to the patient.

It is noted that the above described configuration is the preferable configuration for first and second pivot hinge connecting arms 32A and 32B. 10 However, this is in no way intended to limit the scope of the present invention. Several other alternative configurations of first and second pivot hinge connecting arms 32A and 32B, are within the contemplation of the present invention.

For example, in an alternative arrangement, first and second pivot hinge connecting arms 32A and 32B, may be in a fixed angle relative to one another. 15 Likewise, first and second pivot hinge connecting arms 32A and 32B, may be in an arrangement where there are a series of predefined angles between the two, such that the angle between first pivot hinge connecting arm 32A and the traveling arm 20 is always correspondent with the angle between second pivot hinge connecting arm 32B and the traveling arm 20.

20 In addition to the arrangements regarding the connection of first and second pivot hinge connecting arms 32A and 32B with center pivot hinge 30, various arrangements concerning the connection of first and second pivot hinge connecting

arms 32A and 32B with first and second radial frame connecting arms 42A and 42B and radial frames 44A and 44B are also within the contemplation of the present invention.

For example, center pivot hinge connecting arms 32A and 32B and radial frame connection arms 42A and 42B can also either be formed as four hingedly attached individual elements or they can be formed as two separate fixedly attached portions consisting of connecting arms 32A and 42A and connecting arms 32B and 42B. In the form of hingedly attached elements, the angles between center pivot hinge connecting arms 32A and 32B may vary, with respect to radial frame 5 connection arms 42A and 42B. In the form of fixedly attached elements, the angles between center pivot hinge connecting arms 32A and 32B remains constant, with respect to radial frame connection arms 42A and 42B. 10

Furthermore, radial frames 44A and 44B may either connect fixedly or hingedly to first and second radial frame connection arms 42A and 42B. In the form 15 of a hinged connection, radial frames 44A and 44B may maintain varying angles with respect to first and second radial frame connecting arms 42A and 42B.

Alternatively, when formed as a fixed connection, radial frame connection arms 42A and 42B and radial frames 44A and 44B maintain a constant angle with respect to one another.

20 In one embodiment each radial frame connecting arm 42A, radial frame 44A and pivot hinge connecting arm 32A may be formed as an integrated assembly. Likewise, radial frame connecting arm 42B, radial frame 44B and pivot hinge

connecting arm 32B may also be formed similarly. These two assemblies are then hingedly attached to center pivot hinge 30 at center point (P).

Irrespective of the connectivity arrangements between these elements, as illustrated in Fig. 1, a line drawn from center point (P) at center hinge 30 to the points (P1)and (P2), preferably runs along the longitudinal axes of pivot hinge connecting arms 32A and 32B. Thus, in the preferred configuration, the angles between pivot hinge connecting arms 32A and 32B extending away from center pivot hinge 30 is equal to the angle formed at the top of the triangle formed between center point (P) and coupling rod 80 connection points (P1) and (P2).

It is also noted that the varying manners of connection and angles between connecting arms 32A, 32B, 42A and 42B and radial frames 44A and 44B are all within the contemplation of the present invention. Regardless of the manner of formation however, in order for proper operation of coupling device 10, radial frames 44A and 44B advantageously maintain curvatures having a radius (L), which extend along arc (A), defined by the circle with a radius (L), such that their intersection point always falls at center point (P) at center pivot hinge 30.

In fact, in accordance with one embodiment of the present invention, it is further contemplated that coupling device 10 may be formed without connecting arms 32 and 42 so that radial frames 44 hingedly attach directly to center pivot hinge 30.

For the purposes of describing the salient features of the present invention, center pivot hinge connecting arms 32A and 32B are shown as independently

pivotable about center point hinge 30. Radial frame connecting arms 42A and 42B and radial frames 44A and 44B are described as fixedly connected.

In one embodiment each radial frame connecting arm 42A, radial frame 44A and pivot hinge connecting arm 32A may be formed as an integrated assembly.

5 Likewise, radial frame connecting arm 42B, radial frame 44B and pivot hinge connecting arm 32B may also be formed similarly. The two assemblies are then hingedly attached to center pivot hinge 30 at center point (P).

As illustrated in Fig 1, first and second radial frames 44A and 44B, each maintain tracks 46A and 46B respectively. Tracks 46A and 46B are preferably 10 disposed in the center of radial frames 44A and 44B, however, they alternatively may be formed towards either the upper or lower edges as necessary. Tracks 46A and 46B may be any type of track such as a slot, recessed groove or retaining flange. Likewise, tracks 46A and 46B may be located on either face of radial frames 44A and 44B or even pass entirely through the frames. Any configuration, of tracks, 15 capable of carrying out the desired function of tracks 46A and 46B as described below is within the contemplation of the present invention.

Positioned within each track 46A and 46B, sliding retainers 48A and 48B are slidingly mounted, capable of movement across the entire length of radial frames 44A and 44B.

20 Sliding retainers 48A and 48B are preferably fashioned as cylindrical connectors, attached to tracks 46A and 46B respectively. Each sliding retainer includes a connection bore such as 49A and 49B, through which extension rods or

other cylindrical extensions can pass through. It is further contemplated that sliding retainers 48A and 48B maintain a locking mechanism such as 47A and 47B, that can engage in a locking position when a rod or other cylinder is placed within, preventing any further movement of the rod within the bores. Locking mechanisms 5 47A and 47B may operate in a screw/notch or contracting sleeve arrangement or any other arrangement capable of retarding movement of a rod with sliding retainers, such as sliding retainers 48A and 48B.

In one embodiment of the present invention, sliding retainers 48A and 48B are mounted in a way as to allow movement across the entire length of radial frames 10 44A and 44B respectively. It is also contemplated in the present invention that sliding retainers 48A and 48B may employ various forms of connection with tracks 46A and 46B. For example, sliding retainers 48A and 48B may be mounted so that their movement is at a fixed angle across tracks 46 or they can be mounted so as to allow a pivoting movement in addition to movement along tracks 46.

15 In a first example, sliding retainers 48A and 48B are positioned in a fixed angle with respect to tracks 46. For example, as illustrated in Fig. 1, at any point along radial frames 44A and 44B, sliding retainers 48A and 48B are disposed so that a line, extending through connections bores 49A and 49B, is perpendicular to line tangent to that location along the arc (A) of radial frames 44A and 44B, as 20 illustrated in Fig 1. It should be noted that fixed angles, other than perpendicular to the tangent line, may be used for connection bores 49A and 49B of sliding retainers 48A and 48B is also in the contemplation of the present invention.

In the second example, sliding retainers 48A and 48B are mounted in a way as to allow movement across the entire length of radial frames 44A and 44B respectively. Sliding retainers 48A and 48B are pivotable on pivot axes 45A and 45B where they connect with radial frames 44A and 44B. Thus, sliding retainers 48A and 48B may be rotated about pivot axes 45A and 45B with respect to tracks 5 46A and 46B so as to accept extension rods or other cylinders that enter connection bores 49A and 49B from varying angles, as illustrated in Fig 3.

It is noted that the various components of coupling device 10 may be constructed of any number of different materials such as surgical steel, titanium and rigid polyurethane or plastics. However, this list is in no way intended to limit the 10 scope of the present invention. Coupling devices 10 constructed of any metal or other surgical grade material having similar components is within the contemplation of the present invention as well as a variety of other matters.

During operation, as illustrated in Fig. 2, surgical screws 60A and 60B are 15 inserted below the skin 72 into the spine 70 of a patient. Surgical screws 60A and 60B each have head portions 62A and 62B respectively, configured to accept a coupling rod 80 for the purpose of supporting/connecting a first vertebrae to a second vertebrae in spine 70.

Once coupling device 10 is readied, the patient is prepared for surgery and 20 placed lying down on to a surgical table with the patient's back exposed to the surgeon as illustrated in Fig. 4. In such surgeries for the connection of two

vertebrae, it is necessary to locate the affected vertebrae and identify the appropriate positions to place surgical screws 60A and 60B.

Using x-ray and other techniques, the pedicle of the affected vertebrae is located and drilling points are identified. These two points mark the location, where 5 surgical screws 60A and 60B will eventually be placed.

After the drilling have been identified, an incision is made in the patients back near the two vertebrae to be coupled. The initial incision through the skin and back muscle is small, allowing for a guide wire 90, illustrated in Fig. 5A, to be placed within down to the affected vertebrae. Using fluoroscopy or other similar 10 techniques, the positioning of the guide wire 90 may be verified to ascertain that the initial taps for drilling surgical screws 60A and 60B are properly located.

After guide wire 90 is in place through the skin and muscle, a guide channel 92 is formed so as to allow room for the drilling of surgical screws 60A and 60B. After the incision is made, and guide channel 92 is in place, a series of expanders 15 are used to enlarge guide channel 92 to the appropriate width for drilling surgical screws 60. This is done in this manner so as to limit the incision to the smallest possible size necessary to perform the procedure.

As illustrated in Fig. 5B, after guide channel 92 is formed to the appropriate width, the tip of surgical screws 60 are lowered though guide channel 92 along 20 guide wire 90 down to the affected vertebrae to be drilled. As illustrated in Fig. 5A, the placement of surgical screws 60 is done at an angle into the pedicle of each vertebra at the drilling points so as to gain maximum anchorage. This process is

repeated for both surgical screws 60. When the drill is removed, extensions arms 64A and 64B are left attached to screw heads 62A and 62B.

Thus, in one embodiment of the present invention as illustrated in Fig. 6, the patient is prepared to have the two affected vertebrae connected to one another 5 using coupling device 10. Surgical screws 60A and 60B are each drilled into their respective vertebrae at the identified points with extension rods 64A and 64B, described in more detail below, each extending upwardly from spine 70, through skin 72.

Surgical screws 60A and 60B each maintain removable extension rods 64A 10 and 64B, attached to screw heads 62A and 62B respectively, configured to extend upwardly away from spine 70 and out through skin 72.

Screw heads 62A and 62B maintain linking bores 63A and 63B allowing for connection of surgical screws 60A and 60B by a coupling rod 80 or another similar device. Screw heads 62 with linking bores 63 may be fixed in position relative to 15 surgical screws 60 or they may be free to swivel to allow for better angles with which to accept any connecting rods or devices.

Because extension rods 64A and 64B are attached to surgical screws 60A and 60B, via screw heads 62A and 62B, they may either be in a fixed arrangement or in a moveable arrangement. In the first arrangement, where screw heads 62A and 20 62B are fixed, extension rods 64A and 64B are also fixed such that they extend away from surgical screws 60A and 60B along the screws' longitudinal axes. In the second arrangement, where screw heads 62A and 62B are moveable with relation to

surgical screws 60A and 60B, extension rods 64A and 64B likewise extend away from surgical screws 60A and 60B along the screws' longitudinal axes, but are free to be moved to some extent so as to allow better connection angles with sliding retainers 48A and 48B.

5 In one embodiment of the present invention, as illustrated in Fig. 2, extensions rods 64A and 64B each maintain distance markers 65A and 65B. Distance markers 65 are positioned along extensions rods 64A and 64B at distance (L) away from screw bores 63A and 63B. Thus, distance markers 65A and 65B are positioned at a distance from screw bores 63A and 63B equal to the length (L) of
10 traveling arm 20. Distance markers 65A and 65B are located at this position to mark the point, along extension rods 64A and 64B, at which radial frames 44A and 44B should be located in order for coupling rod 80, to properly align itself with screw bores 63A and 63B as discussed in more detail below.

It should be noted that the components of surgical screws 60A and 60B may
15 be constructed of any number of different materials such as surgical steel, titanium, rigid polyurethane or plastics or any other surgical grade material.

In one embodiment of the present invention, as illustrated in Fig. 3, coupling device 10 is attached to extension rods 64A and 64B. In this process, sliding retainers 48A and 48B are positioned along tracks 46A and 46B so that they align
20 with extension rods 64A and 64B respectively.

As discussed above, there are several variations in the mobility of sliding retainers 48A and 48B as well as in extension rods 64A and 64B. As such, there are

different manners in which coupling device 10 to extension rods 64A and 64B as discussed below.

In a first arrangement, where extension rods 64A and 64B are mounted on pivotable screw heads 62A and 62B, and where sliding retainers 48A and 48B are not pivotable in tracks 46A and 46B, extension rods 64A and 64B are moved away 5 from the axes of surgical screws 60 so that they may properly align with connection bores 49A and 49B of sliding retainers 48.

In a second arrangement, where extension rods 64A and 64B are mounted on fixed screw heads 62A and 62B, and where sliding retainers 48A and 48B are 10 pivotable on pivot axes 45A and 45B in tracks 46A and 46B, sliding retainers 48A and 48B are moved along tracks 46A and 46B and pivoted on pivot axes 45A and 45B so that connection bores 49A and 49B are able to slide over the tops of 15 extension rods 64A and 64B, as illustrated in Fig. 3.

It is noted that additional arrangements may be available such as where both 15 extensions rods 64 and sliding retainers 48 are either pivotable or fixed. However, for the purposes of illustrating the salient features of the present invention, an arrangement where extension rods 64A and 64B are fixed and where sliding retainers 48A and 48B are pivotable is described throughout.

In either case, as illustrated in Fig. 3, coupling device 10, is lowered down 20 extension rods 64A and 64B, allowing the excess material to pass through sliding connectors 48 A and 48B. Coupling device 10 is lowered along extension rods 64A and 64B until the center point of sliding retainers 48A and 48B meets distance

markers 65A and 65B, respectively, each at a distance (L), equal to the length of traveling arm 20, at which point locking mechanisms 47A and 47B secure coupling device 10 in place. It is noted that, as described above, when device 10 is in position, lines drawn from center point (P) at hinge 30 to points (P1) and (P2) at screw bores 63A and 63B, pass through the longitudinal axes of pivot hinge connecting arms 32A and 32B.

Thus, as illustrated in Fig. 7, coupling device 10 is shown in position for operation. Coupling device 10 is mounted on extension rods 64A and 64B at a distance (L) from each screw head 62A and 62B. In this configuration, coupling device 10 is positioned to properly connect surgical screw 60A to surgical screw 60B.

In this respect, a circle, drawn around the top of each of surgical screws 60A and 60B at screw bores 63A and 63B, at points (P1) and (P2) respectively, having a radius (L), would intersect at center point (P) located at center point hinge 30. These circle would each run through the arc (a) of each of the radial frames 44A and 44B respectively.

As such, points (P), the center point, (P1), the screw bore 63A location, (P2), the screw bore 63B location, define a plane in which the connection point of surgical screw heads 62A and 62B reside with the center of coupling device 10.

Furthermore, in this configuration, piercing arm 22, moving in a circle about center point hinge 30, travels in a circle of a radius (L) in the same plane as points (P), (P1) and (P2) and thus, always passes through points (P1) and (P2). As

described below, piercing arm 22 when traveling in this circle around center point hinge 30, is in the proper plane to insert coupling rod 80 and connect surgical screw 60A to surgical screw 60B. As illustrated in Fig. 8, traveling arm 20 is swung down towards surgical screws 60A and 60B, such that piercing arm 22 enters the 5 patient's body and moves first through screw head 62B and next through screw head 62A. Attached to the front of piercing arm 22 is a coupling rod 80 which is moved simultaneously moved through bores 63A and 63B of screw heads 62A and 62B, thus connecting surgical screws 60A and 60B.

After coupling rod 80 is in place, it is fixed in place by further tightening of 10 screw heads 62A and 62B or any other typical connection process. Traveling arm 20 and piercing arm 22 are then removed backwards, swinging around center pivot hinge 30 and leaving coupling rod 80 in place. Extension rods 64A and 64B are then removed from surgical screws 60A and 60B and the patient's incision is closed. Coupling device 10 is uncoupled from extension rods 64A and 64B and prepared for 15 the next surgery.

While only certain features of the invention have been illustrated and described herein, many modifications, substitutions, changes or equivalents will now occur to those skilled in the art. It is therefore, to be understood that this application is intended to cover all such modifications and changes that fall within 20 the true spirit of the invention.